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FEB 2 7 2001

510(k) SUMMARY
Olympus Endoscopic Ligation Device

A. Submitter's Name, Address, Phone and Fax Numbers

1. Manufacturer of the subject devices

Name and Address of manufacturer:	Olympus Optical Co., Ltd. 2-3-1 Shinjyuku Monolis Nishishinjyuku Shinjuku-ku, Tokyo, Japan
Registration No.:	8010047
Address, Phone and Fax Numbers: Of R&D Department, Endoscope Division	2951 Ishikawa-Cho, Hachioji-shi, Tokyo 192-8507 Japan TEL: (426)-42-5101 FAX: (426)-46-2786

B. Name of Contact Person

Name: Address, Phone and Fax Numbers:	Ms. Laura Storms-Tyler Olympus America Inc. Director, Regulatory Affairs Two Corporate Center Drive Melville, New York 11747-3157 TEL: (631) 844-5688 FAX: (631) 844-5416

C. Device Name, Common Name, Classification Name and Predicate Devices

Device Name:	Olympus Endoscopic Ligation Device
Common Name:	Endoscopic Ligation Device
Classification Name:	21 CFR 876.1500 Endoscope and accessories

D. Description of the Device(s)

The Olympus Endoscopic Ligation Device has been designed to be used with an Olympus endoscope to ligate esophageal varices.

The Olympus Endoscopic Variceal Ligation Device is a multiple band ligator composed with two major components.

1. The Distal Attachment
The ligation unit is a distal attachment, which fits to the distal end of the Olympus endoscope. The Ligating Bands are preloaded onto the transparency Cap of the Distal Attachment. The Thread has Anchor Beads for deployment the Ligating Bands, which is held by the Ligating bands. The knot is seated in the hole of the Spool to lock the Thread on the Handle.

2. Handle/Draw Cord
The handle has a function of winder for the Thread, which can be secure onto the Channel Port of the Olympus endoscope. To connect the Thread of the Distal Attachment with the spool, insert the Draw Cord into the Channel of the endoscope until sticking the Hook out the distal end of the scope, catch the Knot of the thread, hold the Ring of the Draw Cord, and withdraw the Draw Cord. To secure the Handle, it is put onto the Port of the endoscope and slide the Locking Clamp to the Lock Position. The handle has the Spool. The Draw cord is attached to the handle for withdrawing the Thread to connect the Spool. The spool with the Knob turns only in the clockwise direction. When the Knob is rotated, the Spool will make a "click" sound, and one band will be fired automatically. The irrigation port is opened on the side wall of the Pedestal Pillar.

E. Intended Use of the Device(s)

The Olympus Endoscopic Ligation device has been designed to be used with an Olympus endoscope to ligate esophageal varices.

F. Summary including Conclusions drawn from Non-clinical Tests

When compared to the similar devices, the Olympus Endoscopic Device does not incorporate any significant changes in intended use, method of operations, material, or design that could affect the safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 7 2001

Ms. Laura Storms-Tyler
Director, Regulatory Affairs & Quality Assurance
Olympus America, Inc.
Two Corporate Center Drive
MELVILLE NY 11747-3157

Re: K001744
Olympus Endoscopic Band Ligation
Dated: December 21, 2000
Received: December 22, 2000
Regulatory Class: II
21 CFR §876.4400/Procode: 78 MND

Dear Ms. Storms-Tyler:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K001744

Device Name: Olympus Endoscopic Ligation Device

Indications for Use:

Olympus Endoscopic Ligation device has been designed to be used with an Olympus endoscope to ligate esophageal varices.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Presciption Use ✓ OR Over-the Counter Use _____
(per 21CFR 801.109)

(Optional Format 1-2-96)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K001744